



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-972/S-023

Wyeth Pharmaceuticals
Attention: Ms. Patricia Kuker Staub
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Kuker Staub:

Please refer to your supplemental new drug application dated May 10, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) 200 mg Tablets.

We acknowledge receipt of your submissions dated April 10, 2003, which constituted a complete response to our December 19, 2002 action letter.

This supplemental new drug application provides for final printed labeling revised to read as follows:

1. Under **WARNINGS/Pulmonary Toxicity**, the following has been added as the new first paragraph:

There have been postmarketing reports of acute-onset (days to weeks) pulmonary injury in patients treated with oral Cordarone with or without initial I.V. therapy. Findings have included pulmonary infiltrates on X-ray, bronchospasm, wheezing, fever, dyspnea, cough, hemoptysis, and hypoxia. Some cases have progressed to respiratory failure and/or death.

2. Under **WARNINGS/Pulmonary Toxicity**, the second paragraph, shown here, has been deleted:

Preexisting pulmonary disease does not appear to increase the risk of developing pulmonary toxicity; however, these patients have a poorer prognosis if pulmonary toxicity does develop.

3. Under **WARNINGS/Pulmonary Toxicity**, the following has been added as the new fourth paragraph:

Patients with preexisting pulmonary disease have a poorer prognosis if pulmonary toxicity develops.

4. Under **WARNINGS/Pulmonary Toxicity**, the word "Recent" has been removed from the beginning of the last sentence of the paragraph that begins with *Interstitial/alveolar pneumonitis*.

5. The following has been added to the **ADVERSE REACTIONS/Postmarketing Reports** section:

...possible fatal respiratory disorders (including distress, failure, arrest, and ARDS), fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates...

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 10, 2003.

At the time of your next printing, please make the following editorial change:

Under **ADVERSE REACTIONS/Postmarketing Reports**, change(b)(4)-----
(b)(4)-----” to “...possibly fatal respiratory disorders...”

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
301-594-5311

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Doug Throckmorton
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